IN THE
UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/501,112	**Confirmation No.**	:	5620
Applicant	:	Benkowski et al.	**Assignee**	:	MICROMED TECHNOLOGY, INC.
Filed	:	07/07/2004			
TC/A.U.	:	3762	**Title**	:	Blood Pump System and Method of Operation
Examiner	:	George R. Evanisko			
Docket No.	:	0021906.023US			
Customer No.	:	22904			

Mail Stop Appeal
Commissioner for Patents
P.O. Box 1450
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APPEAL BRIEF

I. Real party in interest

Robert Benkowski and Gino Morello are the inventors of the claimed inventions. Mr. Benkowski and Mr. Morello have assigned their rights to MICROMED TECHNOLOGY, INC. Therefore, MICROMED TECHNOLOGY, INC. is the real party in interest and is referred to herein as “Appellant.”

II. Related appeals and interferences

None. Neither Appellant or Appellant's legal representative are aware of any appeals or interferences which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. Status of claims

The application was originally filed with claims 1-13. By amendment dated October 15, 2007, claims 1-13 were amended and claims 14-20 were added. By amendment dated March 12, 2008, claims 1-14, 19, and 20 were amended and claims 16-18 were withdrawn. By amendment dated June 20, 2008, claim 1 was amended, claims 16-18 were canceled, and claims 21-23 were added. By amendment dated January 8, 2009 claims 1-3, 5-7, 10-13, and 20 were amended, claims 21-23 were canceled, and claims 24-28 were added. By amendment dated April 22, 2009, claims 1-3, 5-7, 10-13, 19, 20, and 25-28 were amended. Therefore, claims 1-15, 19, 20, and 24-28 are currently pending and stand rejected. The rejections of claims 1-15, 19, 20, and 24-28 are presently being appealed. Claims 16-18 and 21-23 have been canceled. No claims have been allowed.

IV. Status of amendments

No amendment has been filed subsequent to the Final Action dated August 6, 2009, from which this appeal is taken.

V. Summary of claimed subject matter

Independent claim 1 claims a method of controlling a blood pump implanted in a patient (page 2, lines 12-21, and page 7, line 33, through page 8, line 26; figure 6, reference numerals 301 and 302), comprising: operating the pump at a predetermined speed (page 2, lines 15-16, and page 5, lines 17-21); monitoring the patient's pump flow rate (page 2, lines 15-16, and page 4, lines 16-23, and page 8, lines 2-12; figure 6, reference numeral 310); extracting the patient's diastolic pump flow rate from the pump flow rate (page 7, lines 4-7, and page 8, lines 5-8; figure

5, reference numerals 250 and 256, and figure 6, reference numeral 314), wherein the diastolic pump flow rate is a separately isolated flow contribution below a mean pump flow rate (page 6, lines 5-8, and page 7, lines 4-7); and changing the predetermined speed in response to the diastolic pump flow rate (page 7, lines 4-12 and page 8, lines 9-15; figure 6, reference numerals 320, 322, 324, and 326).

Independent claim 7 claims a pump system (page 2, lines 12-21, and page 4, lines 11-29; Figure 3, reference numeral 10), comprising: a pump (page 2, lines 13-14, and page 3, line 28, through page 4, line 10; Figure 2, reference numeral 12, and Figure 3, reference numeral 12); and a controller having an input for receiving a blood pump flow rate signal (page 2, lines 13-14, and page 4, lines 11-23; Figure 3, reference numeral 16), the controller being programmed to extract a separate diastolic pump flow rate from the blood pump flow rate signal (page 7, lines 3-16, and page 8, lines 3-8; Figure 6, reference numeral 314) and provide a control signal to the pump to vary the speed of the pump in response to the separate diastolic pump flow rate (page 6, lines 26-29, and page 7, lines 4-7 and 23-28; Figure 6, reference numerals 320, 322, 324, and 326), wherein the separate diastolic pump flow rate is a flow contribution below a mean flow rate (page 6, lines 5-8, page 7, lines 4-7).

Independent claim 26 claims a method of controlling a blood pump implanted in a patient (page 2, lines 12-21, and page 7, line 33, through page 8, line 26; Figure 6, reference numerals 301 and 302), comprising: monitoring the patient's blood pump flow rate (page 2, lines 15-16, page 4, lines 16-23, and page 8, lines 2-12; Figure 6, reference numeral 310); extracting the patient's diastolic pump flow rate from the pump flow rate (page 7, lines 4-7 and page 8, lines 5-8; Figure 5, numerals 250 and 256, and Figure 6, reference numeral 314), wherein the diastolic

pump flow rate is a separately isolated flow contribution below a mean flow rate (page 6, lines 5-8, page 7, lines 4-7); and changing a speed of the pump in response to the extracted diastolic pump flow rate (page 7, lines 4-12 and page 8, lines 9-15; Figure 6, reference numerals 320, 322, 324, and 326).

VI. Grounds of rejection to be reviewed on appeal

Claims 1-15, 19, and 24-28 stand rejected under 35 U.S.C. 102(e) as being anticipated by Medvedev et al., U.S. Patent Application Publication No. 20040152944. Dependent claim 20 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Medvedev. Appellant appeals each rejection of claims 1-15, 19, 20 and 24-28.

VII. Argument

a. Standard of Review

Decisions of the Patent and Trademark Office (PTO) are reviewed in accordance with the Administrative Procedure Act. *See Dickinson v. Zurko*, 527 U.S. 150, 165 (1999). Thus, the Board's factual findings are reviewed to determine whether they are supported by substantial evidence and the Board's legal conclusions are reviewed de novo. *See In re Gartside*, 203 F.3d 1305, 1315-16 (Fed. Cir. 2000). Because this standard of review is applied to the Board, the Board should apply this standard of review to the Office's rejections.

b. Anticipation

In short, Appellant contends that the Office has failed to make a *prima facie* showing of unpatentability at least because the cited reference (Medvedev) does not teach or suggest "extracting" a "diastolic flow rate" from a mean flow rate. In this regard, Appellant contends that

the Office has erroneously refused to give weight to the positively recited "extracting" claim element.

i. <u>Ground of Rejection</u>

For the convenience of the Board and clarity of purpose, Appellant has reprinted, for both grounds of rejection in the Office Action, the substance of the rejection and the response to arguments in ***bolded and italicized font***. For each ground, Appellant's arguments then follow in regular font.

> ***Claims 1-15, 19, and 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Medvedev et a1 (2004/0152944). Medvedev discloses that the pump speed is changed based on or in response to the diastolic flow rate (e.g. paragraphs 57-61, DQ) and based on the heart rate or pressure (e.g. abstract). In addition, the pump speed is set in accordance with activities, such as sleep, normal activity, or high-energy activity, since the heart rate or other sensed parameters will change in response to these activities affecting the speed of the pump. For claim 19, the system senses pressure through the three feedback waveforms and for claim 8, the system of Medvedev includes an implantable flow measurement device since implantable device measures flow.***
>
> ***...***
>
> ***The argument that Medvedev does not "extract" a diastolic pump flow rate is not persuasive. Medvedev uses a flow rate sensor to sense the pump flow rate. The flow rate sensor uses three input variables, motor current waveform, motor speed waveform, and power source voltage (e.g. paragraphs 48,65) , plus a microcontroller algorithm to determine the flow rate. When the pressure across the pump is a maximum (e.g. para. 59) the diastole/peak minimum flow is "extracted"/determined/used from the flow rate to plug into the DQ equation(s) (along with the separately "extracted" systolic pump flow rate).***
>
> ***The argument that most of the claim limitations are not addressed, such as changing the speed of the pump due to heart rate, is not persuasive. Those limitations are readily apparent and are located throughout the Medvedev reference, such as in the abstract, paragraphs 27,50, etc. The argument that the Medvedev teaches away from some of the pending claim limitations, such as the implantable flow measurement device or pressure sensor, is not persuasive. Medvedev uses an "implantable" device to sense flow and to sense pressure and therefore necessarily has an "implantable" measurement device. The argument that Medvedev teaches against using an implantable pressure sensor or flow sensor is not persuasive. Medvedev states that it removes the technical***

> ***problems associated with "direct" flow sensors (e.g. paragraph 65) and although the pressure sensor and flow sensor of Medvedev may be different than the applicant's sensors, Medvedev's pressure and flow sensors still meet the limitations presented in the claim(s) since they sense pressure and flow.***

ii. <u>Case Law</u>

Appellant recognizes that the Board is well versed in the law of patentability. Therefore, Appellant will not belabor a restatement of the law of anticipation and obviousness. However, Appellant cites the cases below to help focus the Board's review on what Appellant contends is a dispositive issue.

"A claim is anticipated only if each and every element ***as set forth in the claim*** is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). *See also Brown v. 3M*, 265 F.3d 1349, 60 USPQ2d 1375 (Fed. Cir. 2001)("to anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, ***arranged as in the claim***") (emphasis added).

iii. <u>Medvedev</u>

The Office's characterization of what Medvedev discloses and suggests is a factual conclusion that must be supported by substantial evidence. *See Para-Ordnance Mfg., Inc. v. SGS Imp. Int'l, Inc.*, 73 F.3d 1085, 1088 (Fed. Cir. 1995) (holding that the teachings of a prior art reference are underlying factual questions in the obviousness inquiry.)

Medvedev teaches calculating a pump flow rate indirectly, from pump motor parameters, and explicitly teaches away from the use of an implanted flow sensor. Medvedev's calculated flow rate is inherently a composite flow rate, including all flow contributions, as his methodology

is incapable of distinguishing individual flow contributions. Rather, as will be discussed in greater detail below, the best that Medvedev can do is to ***associate*** an average of minimum calculated flow rates, obtained over several cardiac cycles, with ventricular diastole. Thus, contrary to the presently claimed inventions, Medvedev is replete with indirect calculations and associations.

iv. Claims 1 and 26

In contrast to Medvedev, the presently claimed inventions are directed to controlling the pump based on a diastolic pump flow rate that has been extracted from an actual explicitly monitored pump flow rate. For example, claims 1 and 26 each recite (emphasis added):

> "***extracting*** the patient's ***diastolic pump flow rate*** from the pump flow rate, wherein the diastolic pump flow rate is a ***separately isolated flow contribution*** below a ***mean pump flow rate***",

As set forth in paragraph 31, the claimed "diastolic pump [or VAD] flow rate" is defined to be the "flow contribution below the mean VAD [or pump] flow rate." In paragraphs 33-36, the specification further explains, emphasis added:

> [0033] FIG. 4 provides time plots of various physiologic parameters, including heart rate 201, peak systolic VAD flow rate 202, ***mean VAD flow rate 203***, peak diastolic VAD flow rate 204, average peak to peak VAD flow (VAD flow maximum-VAD flow minimum) 205, and average pulsatility index 206. Each plot includes rest 210, exercise onset 212, and exercise conclusion 214 points for the patient. As shown in FIG. 4, the peak diastolic VAD flow plot 204 shows the greatest change in response to the onset and conclusion of exercise.
>
> [0034] Thus, in accordance with embodiments of the invention, the patient's diastolic VAD flow rate is monitored and the controller module 16 is programmed to increase the speed of the pump 12 in response to an increase in diastolic VAD flow, and decrease the pump speed in response to a decrease in diastolic VAD flow. In specific embodiments, the patient's peak diastolic VAD flow rate or average peak diastolic VAD flow rate is monitored and the pump speed is controlled in response thereto.
>
> [0035] FIG. 5 illustrates an analog flow processing system 250 in accordance with an exemplary embodiment of the invention. The system 250 accepts an

> analog voltage input signal 252 that is proportional to blood VAD flow rate and generates a digital output signal 254 to indicate when a patient has begun/finished exercising.
>
> [0036] The VAD flow signal 252 is ac coupled to a precision rectifier 256 to remove the mean VAD flow rate component from the analog VAD flow signal 252. ***The systolic VAD flow rate 260 and diastolic VAD flow rate 261 are extracted separately.*** The isolated systolic and diastolic VAD flow signals 260,261 are then low-pass filtered 262 to yield respective average peak values of the systolic and diastolic VAD flow rates. As noted herein, a patient's peak diastolic VAD flow rate or average peak diastolic VAD flow rate increases during exercise and decreases at rest. Thus, peak diastolic VAD flow rate or the average peak diastolic VAD flow rate is applied to a voltage comparator 264 to compare the signal to a predetermined threshold 266 and provide the binary indication 254 of when the patient is exercising. The pump speed may then be adjusted accordingly.

Thus, as described in the specification, and as claimed, the diastolic flow rate is ***actually extracted*** and ***separately isolated*** as the flow contribution below the mean VAD flow rate such as by use of the system shown in FIG. 5 to result in the separated time plots of FIG. 4.

Appellant contends that the Office erred in reaching the factual conclusion that Medvedev teaches "***extracting*** the patient's diastolic pump flow rate from the pump flow rate, wherein the diastolic pump flow rate is a ***separately isolated flow contribution*** below a mean pump flow rate", emphasis added, as claimed in claims 1 and 26. More specifically, the Office's error is displayed in its conclusion that "[w]hen the pressure across the pump is a maximum (e.g. para. 59) the diastole peak minimum flow is 'extracted'/determined used from the flow rate" is equivalent to ***extracting*** a ***separately isolated*** flow contribution. Page 4 of the August 6, 2009 Final Office Action.

The Office's factual conclusion is error in multiple respects. First, and at the very least, even if Medvedev teaches "extracting" (a conclusion to which Appellant does not accede), Medvedev does not teach "extracting … diastolic pump flow rate from the pump flow rate" "***as set forth in the claim***", as is required for anticipation. For example, nowhere does Medvedev

teach extracting any flow rate from another. Furthermore, nowhere does Medvedev teach "wherein the diastolic pump flow rate is a ***separately isolated flow contribution*** below a ***mean pump flow rate***", as claimed.

Second, and more fundamentally, while Medvedev discusses average minimum peaks being "associated with ventricular diastole", nowhere does he actually teach "***extracting*** the patient's diastolic pump flow rate as the flow contribution below a mean pump flow rate", emphasis added, as claimed in claims 1 and 26. More specifically, Medvedev's one and only use of the word "diastole", or any variant thereof, is found in his paragraph 59, reproduced below:

> [0059] where $Q_{peak(-)}$ is the average of the peak minimum instantaneous flow rates within each cardiac cycle recorded over a given control cycle. This peak minimum flow is associated with ventricular diastole when the pressure across the pump is maximum.

Thus, Medvedev is only concerned with the average of the minimum peaks (over multiple cardiac cycles), which he ***associates*** with ventricular diastole, rather than an actual ***extracted or separately isolated diastolic flow rate***. More specifically, Medvedev teaches calculating and monitoring a ***composite*** flow rate determined from a power calculation. *See*, for example, paragraphs [0033], [0039], [0048], and [0065]. Medvedev then looks for maximum and minimum peaks in that calculated ***composite*** flow rate, averages the maximum and minimum peaks, and uses those average ***peaks*** in his invention.

In any case, nowhere does Medvedev, or any of the previous prior art references made of record, actually teach "***extracting*** the patient's diastolic pump flow rate from the pump flow rate, wherein the diastolic pump flow rate is a ***separately isolated flow contribution*** below a mean pump flow rate", emphasis added, as claimed in claims 1 and 26. While Medvedev does calculate/determine the pump flow rate, Medvedev never takes the next step. Namely,

Medvedev never ***extracts or separately isolates*** the patient's diastolic pump flow rate, or systolic pump flow rate, from his calculated/determined pump flow rate. At most, Medvedev looks at the calculated/determined composite flow waveform, and "associates" an "average of the peak minimum[s]" with diastole. This is simply not the same thing as "***extracting*** the patient's diastolic pump flow rate from the pump flow rate, wherein the diastolic pump flow rate is a ***separately isolated flow contribution*** below a mean pump flow rate", emphasis added, as claimed in claims 1 and 26. At the very least, this limitation is not described in Medvedev as set forth in the claims.

In addition to not being "as set forth in the claim," Medvedev's approach can be problematic. For example, in highly irregular flow waveforms and in those exhibiting large negative excursions, such as ventricular suction, the average of those peaks will be significantly lower than an actual measured diastolic flow rate. This divergence can cause a system, such as Medvedev's, to overreact.

Thus, it cannot be said that "each and every element as set forth in the claim is found, either expressly or inherently described, in" Medvedev, as is required by the applicable case law. As a result, Medvedev simply does not anticipate "***extracting*** the patient's diastolic pump flow rate from the pump flow rate, wherein the diastolic pump flow rate is a ***separately isolated flow contribution*** below a mean pump flow rate", emphasis added, as claimed in claims 1 and 26.

v. <u>Claims 3 and 6</u>

In contrast to Medvedev, the presently claimed inventions also use distinctly different control schemes. For example, claims 3 and 6 each recite "wherein changing the predetermined speed includes increasing the pump speed in response to an increase in the

diastolic pump flow rate."

No mention of this specific limitation is made in the Office Action. Rather, the Office erroneously asserts that this limitation is "readily apparent and located throughout the Medvedev reference, such as in the abstract, paragraphs 27, 50, etc."

However, Appellant can find no mention of this limitation in Medvedev. More specifically, while Medvedev does teach controlling pump speed based on his calculated ***composite*** flow rate, Appellant can find no discussion in Medvedev of ***increasing*** the pump speed in response to an ***increase*** in diastolic flow rate, as claimed. In fact, the only mention Appellant can find of increasing the pump speed in response to anything even "associated" with any diastolic flow rate is in paragraph [0077]. Medvedev's paragraph [0077] teaches "[i]f $Q_{peak(-)}$ [which is associated with ventricular diastole] < Q_{min}, then power is increased". Thus, Medvedev's paragraph [0077] appears to suggest ***increasing*** the pump speed in response to a ***decrease*** in what might be associated with a diastolic flow rate. This is the ***opposite*** of what is claimed and may injure a patient because ventricular suck down may often be characterized by flow waveforms with large negative excursions. In other words, it has been found that ***increasing*** pump speed in response to a ***decrease*** in diastolic flow rate, as Medvedev apparently suggests, may potentially drive the patient into further suction.

This is one of the key distinctions between the present invention and the prior art. For example, many clinicians thought that as the mean flow increased so did the peak positive and peak negative values, effectively sliding the entire waveform more positive. However, it has been found that in many patients this simply does not occur. Therefore, a system such as Medvedev's may simply fail to react properly.

In any case, it cannot be said that "each and every element as set forth in the claim is found, either expressly or inherently described, in" Medvedev, as is required by the applicable

case law. As a result, Medvedev simply does not anticipate "wherein changing the predetermined speed includes increasing the pump speed in response to an increase in the diastolic pump flow rate", as claimed in claims 3 and 6.

vi. Claim 4

Claim 4 recites "wherein changing the predetermined speed includes increasing the pump speed in response to an increase in the heart rate."

No mention of this limitation is made in the Office Action. Appellant can find no mention of this limitation in Medvedev. More specifically, Appellant can find no discussion in Medvedev of increasing the pump speed in response to an increase in heart rate.

Thus, it cannot be said that "each and every element as set forth in the claim is found, either expressly or inherently described, in" Medvedev, as is required by the applicable case law. As a result, Medvedev simply does not anticipate "wherein changing the predetermined speed includes increasing the pump speed in response to an increase in the heart rate", as claimed in claim 4.

vii. Claim 7

Claim 7 recites "a controller having an input for receiving a blood pump flow rate signal, the controller being programmed to ***extract a separate diastolic pump flow rate*** from the blood pump flow rate signal", emphasis added. Thus, like claims 1 and 26, claim 7 requires a ***diastolic*** flow rate to be extracted from a flow rate. Furthermore, claim 7 explicitly requires the diastolic flow rate to be ***separated*** from the blood pump flow rate signal. As discussed above, this is described in paragraphs 33-36 of the specification, and most explicitly in paragraph 36:

[0036] The VAD flow signal 252 is ac coupled to a precision rectifier 256 to

> remove the mean VAD flow rate component from the analog VAD flow signal 252. ***The systolic VAD flow rate 260 and diastolic VAD flow rate 261 are extracted separately.*** The isolated systolic and diastolic VAD flow signals 260,261 are then low-pass filtered 262 to yield respective average peak values of the systolic and diastolic VAD flow rates. As noted herein, a patient's peak diastolic VAD flow rate or average peak diastolic VAD flow rate increases during exercise and decreases at rest. Thus, peak diastolic VAD flow rate or the average peak diastolic VAD flow rate is applied to a voltage comparator 264 to compare the signal to a predetermined threshold 266 and provide the binary indication 254 of when the patient is exercising. The pump speed may then be adjusted accordingly. (emphasis added)

Appellant contends that the Office erred in reaching the factual conclusion that Medvedev teaches “a controller having an input for receiving a blood pump flow rate signal, the controller being programmed to ***extract a separate diastolic pump flow rate*** from the blood pump flow rate signal”, emphasis added, as claimed in claim 7. More specifically, the Office’s error is displayed in its conclusion that “[w]hen the pressure across the pump is a maximum (e.g. para. 59) the diastole peak minimum flow is ‘extracted’/determined used from the flow rate” is equivalent to ***extracting*** a ***separate*** diastolic pump flow rate. Page 4 of the August 6, 2009 Final Office Action. At the very least, this is simply not “***as set forth in the claim***”, as is required for anticipation.

For example, as discussed above, Medvedev’s controller calculates his flow rate, and therefore does not have the claimed “input for receiving a blood pump flow rate signal,” nor any need thereof. In fact, as will be discussed in greater detail below, Medvedev explicitly teaches away from anything external to his controller providing a flow rate signal, and therefore Medvedev explicitly teaches away from “a controller having an input for receiving a blood pump flow rate signal,” as claimed.

Furthermore, as discussed above, while Medvedev does mention an association with ventricular diastole, nowhere does he actually teach any “controller being programmed to

extract a separate diastolic pump flow rate from the blood pump flow rate signal", emphasis added, as claimed in claim 7. In fact, Medvedev merely uses a calculated composite flow rate, with no effort being made to extract, much less separately extract a diastolic flow rate from a flow rate signal. At the very least, as discussed above, this limitation is not described in Medvedev as set forth in the claim.

Thus, it cannot be said that "each and every element as set forth in the claim is found, either expressly or inherently described, in" Medvedev, as is required by the applicable case law. As a result, Medvedev simply does not anticipate "the controller being programmed to ***extract a separate diastolic pump flow rate*** from the blood pump flow rate signal", emphasis added, as claimed in claim 7.

viii. <u>Claim 8</u>

Claim 8 recites "further comprising an ***implantable flow measurement device*** having an ***output for providing the flow rate signal***", emphasis added. Claim 8 depends from claim 7, which also recites "a pump" and "a controller having an ***input for receiving a blood pump flow rate signal***", emphasis added. Thus, claim 8 explicitly requires three components, a pump, a controller with a input, and a flow measurement device

As an initial matter, Appellant feels compelled to point out that Medvedev simply does not actually use a flow rate sensor, as erroneously asserted by the Office on page 4 of the August 6, 2009 Final Office Action. More specifically, the Office erred in concluding that "Medvedev includes an implantable flow ***measurement*** device", emphasis added, erroneously suggesting that because Medvedev ***calculates*** flow he meets this limitation. Page 2 of the August 6, 2009 Final Office Action. Furthermore, the Office fails to point out how Medvedev teaches providing either "an ***input for receiving a blood pump flow rate signal***" or "an ***output***

for providing the flow rate signal". At the very least, Medvedev teaches away from these elements "***as set forth in the claim***".

Rather, as discussed above, Medvedev calculates flow and/or pressure from the current, voltage, and/or speed of his pump. As will be discussed in greater detail below, significant accuracy issues arise when using a derived/determined/calculated flow. For example, in the event there is a flow obstruction, bearing problem, or the like, the derivation will calculate an erroneous flow rate based on the given current, voltage, and/or speed of the pump.

In any case, Medvedev actually teaches away from this claim limitation. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994); *See* also *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 416, (2007).

In the present case, Medvedev explicitly discourages the use of the claimed sensor. For example, as stated in paragraph [0025], Medvedev "proposes … using no pressure or ECG type sensors (so-called "sensorless" approach)." In paragraph [0080], Medvedev again states that he prefers to use "no pressure or flow sensors". Medvedev advocates his approach because, as explained in paragraph [0005] other systems "require extra hardware inside the patient and increase the risk of complication." For example, in paragraph [0065], Medvedev states that deriving suction based on intrinsic pump signals "removes the technical and reliability problems associated with direct flow, pressure and heart rate sensing". Thus, Medvedev's goal is to provide a system with no extra hardware inside the patient in an effort to decrease the risk of complication. As a result, because Medvedev repeatedly discourages the use of the claimed sensor, Medvedev explicitly teaches away from a system including the claimed flow sensor.

This is an important distinction because algorithms which utilize intrinsic pump signals to

detect suction, such as Medvedev's, are inherently dependent on the pump's ability to react to changes in load. Therefore they are intrinsically slower in responding to short duration events, such as imminence of suction, due to the angular momentum (gyroscopic effect) of the rotor impeller. Suction detection algorithms implemented with intrinsic pump signals, such as current and speed, derived from pumps with more massive rotors or with rotors which spin faster will be slower in response than algorithms based on independent measurements, such as blood flow rate. This effectively induces a low pass filtering affect on the pump's intrinsic speed, current, and voltage values, which can mask sudden changes in flow that would be measured with the claimed flow sensor.

Additionally, due to non-linearities in a pump's flow versus differential pressure versus current versus speed characteristics, current and power alone ***cannot*** adequately indicate suction. Pumps systems which may have bearing wear, mechanical failures, thrombosis, kinked grafts, or other occlusions, etc. will assuredly cause a flow derivation algorithm based on power and speed to yield erroneous results. Erroneously elevated power levels would be the most likely result and will simply convince the algorithm that the pump is operating somewhere else on it's characteristic/performance curve. Clinically, in this event, the control system would most likely ***lower*** the pump speed to keep the calculated flow rate constant which could yield a physiologically lower flow than desired, perhaps placing the patient at risk. Thus, Medvedev's teaching away from including an actual flow sensor can be very dangerous for patients, especially those whose anticoagulation regimen is not properly controlled or who have other difficulties.

The present invention's inclusion of the flow meter and/or pressure sensor, against the teaching of Medvedev, may provide a true, calibrated metric of blood flow with a sufficiently high bandwidth to quickly capture subtle changes in blood flow rate, such as those expected during

suction events where there are rapid negative excursions in blood flow rate. Furthermore, patients in the immediate post-operative phase, or those with significantly compromised ventricular function, may not generate adequate, if any, flow waveform pulsatility. In this case Medvedev's algorithmic approach may falsely detect suction and drive pump speed down to the point where the patient is not adequately supported and injured. Thus, the present invention provides a distinct advance over, and is explicitly taught away from by, the prior art.

In any case, not only does Medvedev fail to teach a system "further comprising an implantable flow measurement device having an output for providing the flow rate signal", as shown above, Medvedev actually teaches away from including "an implantable flow measurement device having an output for providing the flow rate signal", as claimed. In fact, Medvedev teaches calculating flow, within his microprocessor, and therefore has no "output for providing the flow rate signal", much less an output feeding an input on any controller, as claimed.

Thus, it cannot be said that "each and every element as set forth in the claim is found, either expressly or inherently described, in" Medvedev, as is required by the applicable case law. As a result, Medvedev simply does not anticipate "further comprising an implantable flow measurement device having an output for providing the flow rate signal", as claimed in claim 8.

ix. <u>Claim 10</u>

Claim 10 recites "wherein the controller is programmed to increase the speed of the pump in response to an increase in the separate diastolic pump flow rate."

No mention of this specific limitation is made in the Office Action. Rather, the Office merely asserts that this limitation is "readily apparent and located throughout the Medvedev reference, such as in the abstract, paragraphs 27, 50, etc."

However, Appellant can find no mention of this limitation in Medvedev. More specifically, while Medvedev does teach controlling pump speed based on his calculated ***composite*** flow rate, Appellant can find no discussion in Medvedev of ***increasing*** the pump speed in response to an ***increase*** in diastolic flow rate, as claimed. In fact, the only mention Appellant can find of increasing the pump speed in response to anything even "associated" with any diastolic flow rate is in paragraph [0077]. Medvedev's paragraph [0077] appears to suggest ***increasing*** the pump speed in response to a ***decrease*** in what might be associated with a diastolic flow rate. As discussed above, this is the opposite of what is claimed and may actually drive the patient into further suction.

Thus, it cannot be said that "each and every element as set forth in the claim is found, either expressly or inherently described, in" Medvedev, as is required by the applicable case law. As a result, Medvedev simply does not anticipate "wherein the controller is programmed to increase the speed of the pump in response to an increase in the separate diastolic pump flow rate", as claimed in claim 10.

x. <u>Claim 12</u>

Claim 12 recites "wherein the controller is programmed to increase the speed of the pump in response to an increase in at least one of the separate diastolic pump flow rate or the heart rate."

No mention of this specific limitation is made in the Office Action. Rather, the Office merely asserts that this limitation is "readily apparent and located throughout the Medvedev reference, such as in the abstract, paragraphs 27, 50, etc."

However, Appellant can find no mention of this limitation in Medvedev. More specifically, while Medvedev does teach controlling pump speed based on his calculated

composite flow rate, Appellant can find no discussion in Medvedev of ***increasing*** the pump speed in response to an ***increase*** in diastolic flow rate or heart rate, as claimed. In fact, the only mention Appellant can find of increasing the pump speed in response to anything even "associated" with any diastolic flow rate is in paragraph [0077]. Medvedev's paragraph [0077] appears to suggest ***increasing*** the pump speed in response to a ***decrease*** in what might be associated with a diastolic flow rate. As discussed above, this is the opposite of what is claimed and may actually drive the patient into further suction.

Thus, it cannot be said that "each and every element as set forth in the claim is found, either expressly or inherently described, in" Medvedev, as is required by the applicable case law. As a result, Medvedev simply does not anticipate "wherein the controller is programmed to increase the speed of the pump in response to an increase in at least one of the separate diastolic pump flow rate or the heart rate", as claimed in claim 12.

xi. <u>Claim 19</u>

Claim 19 recites "further comprising an implantable pressure sensor for providing pressure sensor data to the controller."

As discussed above, the Office erred in asserting Medvedev's "system senses pressure through three feedback waveforms", erroneously suggesting that because Medvedev ***calculates*** pressure he meets this limitation. Page 2 of the August 6, 2009 Final Office Action. More specifically, the Office fails to point out how Medvedev teaches "providing pressure sensor data to the controller", as claimed in claim 19. As discussed above, Medvedev simply does not actually use a flow rate sensor, and in fact explicitly teaches away there from. At the very least, Medvedev teaches away from this element "***as set forth in the claim***".

As discussed above, Medvedev explicitly discourages the use of the claimed sensor. *See*, for example, paragraphs [0025], [0065], and [0085]. As a result, because Medvedev repeatedly discourages the use of the claimed sensor, Medvedev explicitly teaches away from a system including the claimed pressure sensor.

As also discussed above, this is an important distinction because algorithms which utilize intrinsic pump signals are inherently dependent on the pump's ability to react to changes in load and cannot adequately account for non-linearities between a pump's flow, differential pressure, current, power, and speed characteristics. Furthermore, pressures may be dependent on the state of the patient's aortic valve and the speed of the pump. Pressures derived arithmetically, such as from current, voltage, and speed as Medvedev teaches, may not be able to adequately account for the condition of the patient's aortic valve, and may therefore lead to erroneous results, further risking patient care.

In any case, not only does Medvedev fail to teach a system "further comprising an implantable pressure sensor for providing pressure sensor data to the controller", as shown above, Medvedev actually teaches away from including "an implantable pressure sensor", as claimed. Rather, Medvedev teaches ***calculating*** pressure, within his microprocessor, and therefore has nothing actually "providing pressure sensor data to the controller", as claimed.

Thus, it cannot be said that "each and every element as set forth in the claim is found, either expressly or inherently described, in" Medvedev, as is required by the applicable case law. As a result, Medvedev simply does not anticipate "further comprising an implantable pressure sensor for providing pressure sensor data to the controller", as claimed in claim 19.

xii. <u>Claim 27</u>

Claim 27 recites "increasing the speed of the pump in response to an increase in the

extracted diastolic pump flow rate."

No mention of this specific limitation is made in the Office Action. Rather, the Office merely asserts that this limitation is "readily apparent and located throughout the Medvedev reference, such as in the abstract, paragraphs 27, 50, etc."

However, Appellant can find no mention of this limitation in Medvedev. More specifically, while Medvedev does teach controlling pump speed based on his calculated ***composite*** flow rate, Appellant can find no discussion in Medvedev of ***increasing*** the pump speed in response to an ***increase*** in diastolic flow rate, as claimed. In fact, the only mention Appellant can find of increasing the pump speed in response to anything even "associated" with any diastolic flow rate is in paragraph [0077]. Medvedev's paragraph [0077] appears to suggest ***increasing*** the pump speed in response to a ***decrease*** in what might be associated with a diastolic flow rate. As discussed above, this is the opposite of what is claimed and may actually drive the patient into further suction.

Thus, it cannot be said that "each and every element as set forth in the claim is found, either expressly or inherently described, in" Medvedev, as is required by the applicable case law. As a result, Medvedev simply does not anticipate "increasing the speed of the pump in response to an increase in the extracted diastolic pump flow rate", as claimed in claim 27.

c. <u>Obviousness</u>

i. <u>Ground of Rejection</u>

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Medvedev et al. Medvedev discloses the claimed invention except for sensing of diastolic flow rate from the sensed pressure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable pump and method as taught by Medvedev, with the sensing of diastolic flow rate from the sensed pressure since it was known in the art/the examiner is taking official notice that implantable

> ***pumps and methods use the sensed pressure to determine diastolic flow rate to provide the predictable results of a conventional way to easily determine the flow rate from sensed pressure without using other flow sensors.***

ii. <u>Case Law</u>

The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). *See also KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 82 USPQ2d 1385, 1396 (2007).

Further, official notice unsupported by documentary evidence should only be taken by the Office where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the Office must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)).

iii. <u>Claim 20</u>

As an initial matter, Appellant must point out that Medvedev never actually senses flow or pressure, as discussed above. Rather, Medvedev calculates flow and/or pressure from the current, voltage, and/or speed of his pump.

Claim 20 recites “wherein the pressure sensor data from the pressure sensor is used to derive separate diastolic pump flow rate information.” Claim 20 depends from claim 19, which depends from claim 7. Claim 19 recites “further comprising an implantable pressure sensor for providing pressure sensor data to the controller.” Thus, claim 20 requires “an implantable

pressure sensor for providing pressure sensor data to the controller", with that sensor data being "used to derive separate diastolic pump flow rate information."

The Office erred in failing to provide "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness", as is required for a legal conclusion of obviousness. On its face, the Office's reasoning appears rational. However, upon closer examination, the supporting underpinning is fatally flawed.

As discussed at length above, Medvedev never even derives "separate diastolic pump flow rate information". Medvedev never breaks down his calculated composite flow. Additionally, as also discussed at length above, Medvedev actually and explicitly teaches away from including "an implantable pressure sensor". This is important because the claim requires an actual "sensor for ***providing pressure sensor data <u>to</u> the controller***", emphasis added.

Furthermore, Medvedev teaches pressure being derived from flow, not the other way around, as claimed. *See*, for example, paragraph [0035]. Of course, as discussed at length above, Medvedev's flow itself is dubiously ***calculated***, and therefore any further calculation of pressure, from calculated flow, could further compound the problems discussed above. In any case, Medvedev's calculation of pressure from a calculated flow is significantly different than the claimed "an implantable pressure sensor for providing pressure sensor data to the controller", with that sensor data being "used to derive separate diastolic pump flow rate information", as claimed.

Thus, Medvedev simply cannot be said to support a legal conclusion of obviousness of "an implantable pressure sensor for providing pressure sensor data to the controller", much less where that pressure sensor data being "used to derive separate diastolic pump flow rate information", as claimed. In fact, Medvedev actually teaches away from this combination of claim limitations, and therefore the present obviousness rejection simply cannot be sustained.

For at least these reasons, Appellant respectfully submits that the presently pending claims are patentable over the disclosure and teaching of the prior art made of record. These rejections are therefore appealed and Assignee respectfully requests they be overruled.

Respectfully submitted,

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VIII. Claims appendix

1. A method of controlling a blood pump implanted in a patient, comprising:

operating the pump at a predetermined speed;

monitoring the patient's pump flow rate;

extracting the patient's diastolic pump flow rate from the pump flow rate, wherein the diastolic pump flow rate is a separately isolated flow contribution below a mean pump flow rate; and

changing the predetermined speed in response to the diastolic pump flow rate.

2. The method of claim 1, further comprising:

monitoring the patient's heart rate; and

changing the predetermined speed in response to the heart rate.

3. The method of claim 1, wherein changing the predetermined speed includes increasing the pump speed in response to an increase in the diastolic pump flow rate.

4. The method of claim 2, wherein changing the predetermined speed includes increasing the pump speed in response to an increase in the heart rate.

5. The method of claim 1, wherein changing the predetermined speed includes decreasing the pump speed in response to a decrease in the diastolic pump flow rate.

6. The method of claim 2, wherein changing the predetermined speed includes increasing the pump speed in response to an increase in the diastolic pump flow rate.

7. A pump system, comprising:

a pump; and

a controller having an input for receiving a blood pump flow rate signal, the controller being programmed to extract a separate diastolic pump flow rate from the blood pump flow rate signal and provide a control signal to the pump to vary the speed of the pump in response to the separate diastolic pump flow rate, wherein the separate diastolic pump flow rate is a flow contribution below a mean flow rate.

8. The pump system of claim 7, further comprising an implantable flow measurement device having an output for providing the flow rate signal.

9. The pump system of claim 7, wherein the controller is further programmed to vary the speed of the pump in response to heart rate changes.

10. The pump system of claim 7, wherein the controller is programmed to increase the speed of the pump in response to an increase in the separate diastolic pump flow rate.

11. The pump system of claim 7, wherein the controller is programmed to decrease the speed of the pump in response to a decrease in the separate diastolic pump flow rate.

12. The pump system of claim 9, wherein the controller is programmed to increase the speed of the pump in response to an increase in at least one of the separate diastolic pump flow rate or the heart rate.

13. The pump system of claim 12, wherein the controller is programmed to decrease the speed of the pump in response to a decrease in the separate diastolic pump flow rate.

14. The method of claim 1, further comprising:

setting the predetermined speed of the pump in accordance with activities performed by the patient.

15. The method of claim 14, wherein the activities are sleeping, normal activity or high energy exertion.

19. The pump system of claim 7, further comprising an implantable pressure sensor for providing pressure sensor data to the controller.

20. The pump system of claim 19, wherein the pressure sensor data from the pressure sensor is used to derive separate diastolic pump flow rate information.

24. The method of claim 2, wherein changing the predetermined speed includes decreasing the pump speed in response to a decreasing in the heart rate.

25. The method of claim 2, wherein changing the predetermined speed includes decreasing the pump speed in response to a decrease in the diastolic pump flow rate.

26. A method of controlling a blood pump implanted in a patient, comprising:

monitoring the patient's blood pump flow rate;

extracting the patient's diastolic pump flow rate from the pump flow rate, wherein the diastolic pump flow rate is a separately isolated flow contribution below a mean flow rate; and

changing a speed of the pump in response to the extracted diastolic pump flow rate.

27. The method of claim 26, further including the step of increasing the speed of the pump in response to an increase in the extracted diastolic pump flow rate.

28. The method of claim 26, further including the step of decreasing the speed of the pump in response to a decrease in the extracted diastolic pump flow rate.

IX. Evidence appendix

None.

X. Related proceedings appendix

None.